REMARKS / ARGUMENTS

Reconsideration of the subject application, as amended, is respectfully requested.

The claims of the subject application are directed to apparatus and methods for dermatologic treatments in which a light source and optical diffuser are employed to provide a light pulse having an output fluence of not less than 4 J/cm^2 and an integrated radiance which has been reduced to an eye-safe value.

Claims 1-78 are pending in the subject application. Claims 3 and 15 have been amended to substitute descriptive wording for the trademarks SPECTRALON (claims 3 and 15) and DURAFLECT (claim 15) appearing in the originally filed claims. Support for these amendments can be found at page 23, lines 19 to 29 of the subject application.

Official Action

The Examiner has rejected claims 71-77 under 35 U.S.C. 112, second paragraph as "indefinite as they simultaneously require the output pulses to be greater than 4.0 and less than 0.6 J/cm^2." The Examiner has also rejected claims 13 and 15 under 35 U.S.C. 112, second paragraph as "indefinite due to use of the trademark SPECTRALON."

The Examiner has rejected claims 1, 2, 5, 8, 16-18, 20-34, 36-44 under U.S.C. 102(b) as being anticipated by USP 5,743,901 to Grove et al. (Grove et al. '901).

The Examiner has rejected claims 45-70 under U.S.C. 103(a) as being unpatentable over Grove et al ('901) in combination with USP 5,707,403 to Grove et al (Grove et al. '403).

The Examiner has rejected claims 3, 4, and 11-15 under U.S.C. 103(a) as being unpatentable over Grove et al ('903) [believed to be Grove et al. '901] in combination with USP 5,966,210 to Rosow et al.

The Examiner has rejected claims 6, 7, 9, 10, 19 and 35 under 35 U.S.C. 103(a) as being unpatentable over Grove et al ('903) [believed to be Grove '901] in view of USP 5,663,659 to McDaniel.

Applicants respectfully traverse these rejections for the reasons set forth below.

Rejection of claims 71-77:

It is respectfully submitted that claims 71 – 78, as worded are definite. Applicants note that the recited 4.0 J/cm^2 figure of element (d) of claim 71, for example, refers to an output fluence of the device, while the 0.6003 J/cm^2 figure calculated by the Examiner used the statement of eye safety for the Maximum Permissible Exposure (MPE), which refers to the fluence at the eye produced by the device when measured according to published international standards. It is respectfully submitted that an "output fluence" of the device does not represent the same value as "MPE" and that it is possible to have an output fluence of greater than 4 J/cm^2, while simultaneously producing a fluence at the eye well below the MPE.

The distinction is further clarified by reference to several passages in the subject application. Output fluence is defined on page 40, lines 14-16, of the subject application:

> Throughout this patent application the term output fluence is intended to describe the fluence at the output aperture or output window of the dermatologic treatment apparatus. For purposes of clarification, the output fluence of the device is also termed below as F_{source}.

Maximum permissible exposure is discussed on page 47, line 20 through page 48, line 4, of the subject application:

> To evaluate eye safety under the ANSI, IEC or ICNIRP guidelines, two values are calculated and compared. The first is the Maximum Permissible Exposure (MPE). This value is the fluence or irradiance that is considered safe for the human eye, measured at the cornea. The actual value of the MPE varies greatly depending on the characteristics of the light source in question . . . .
>
> The second value "F_{cornea}" is the fluence produced at the cornea from a particular light source, as measured through a pair of apertures limiting the angle of acceptance to 100 milliradians . . . . The value of F_{cornea} depends on both

the fluence produced by the device at its output (the "output fluence"), as well as how the light diverges from the output as it propagates toward the eye. For any light source, if F_{cornea} is less than the MPE for all possible distances between the source and the eye, the device is considered eye-safe.

Thus, the output fluence of a light source (F_{source}), the fluence this light source would produce at the cornea (F_{cornea}, measured as defined in the international standards), and the MPE associated with this light source, are all quite different values. Therefore, the basis for the Examiner's rejection of claims 71-78 as indefinite under 35 U.S.C. 112, second paragraph -- that the output fluence value recited is greater than the MPE value calculated -- does not indicate inconsistent quantities. In other words, it is entirely possible for output fluences of not less than 4 J/cm^2 to result in eye-safe values under an MPE calculation, given the other conditions set forth in the limitations of the claims.

Claims 71-78 therefore recite consistent conditions and are definite.

Use of Trademark SPECTRALON

As to the Examiner's rejection of claims 3 and 15 under 35 U.S.C. 112, second paragraph, as indefinite because of the use of the trademark "SPECTRALON," it is believed that the Examiner meant to refer to claim 4 rather than claim 3. Assuming that is the case, claims 4 and 15 have been amended to substitute the phrase "other thin diffuse reflectance material" for the trademark SPECTRALON. Also, claim 15 has been amended to substitute the phrase "low absorption applied surface coatings" for the trademark DURAFLECT.

For the above reasons, it is respectfully submitted that the Examiner's rejections under 35 U.S.C. 112, second paragraph have been overcome.

Rejection Under 35 U.S.C. 102(b)

In rejecting claims 1, 2, 5, 8, 16-18, 20-34, 36-44 under U.S.C. 102(b), the Examiner has cited Figures 1 and 2, and column 1, line 30 to column 3, line 20; column

4, line 11-22; and column 5, line 66 to column 7, line 37; of Grove et al. '901, and asserted that "[t]he device is 'configured' for various treatments, since it can apply light to the various tissues desired to be treated and the device 'has a fluence at the eye of a person less than the maximum permissible exposure . . .' for people more than a mile away from the device." Applicants respectfully traverse this rejection because Grove et al. '901 do not teach the use of a "divergent light source" and "optical diffuser" (claim 1), or "light source" and "optical diffuser" (claim 31), so as to produce eye-safe light pulses. This is confirmed by fact that the Examiner has had to resort to an excessively large separation of "more than a mile from the device" of Grove et al. '901 in order to be able to identify a location at which the device could be characterized as having a fluence at the eye of less than the maximum permissible exposure. By implication, the Examiner concedes that for distances less than a mile, the device of Grove et al. '901 produces a fluence having an integrated radiance sufficient to cause eye damage; and concedes that the device does not meet the claim 1 and 31 requirements of an optical diffuser positioned along the light path in the device such that the output light pulse has an integrated radiance reduced to an eye safe value.

In particular, the passages cited by the Examiner from Grove et al. '901 teach laser diode/microlens combinations in which the primary thrust is to increase the effective brightness of a diode laser array by minimizing divergence and maximizing throughput. For example, column 6, lines 4-10, of Grove et al. '901 discuss reducing divergence from diode laser bars, and using fiber microlenses attached to diode laser arrays to reduce the area solid-angle product of the arrays by a factor of twenty. Grove et al. '901, thus, teach increasing the brightness of the array output by reducing divergence, rather than the eye safe features of recited in claims 1 and 31 of providing a output light pulse which has been subjected to an optical diffuser to reduce the integrated radiance of the output light pulses to an eye-safe value. Grove et al. '901 therefore teaches away from the limitations of claims 1 and 31. Indeed, the Examiner's recognition that a separation distance or of "more than a mile away" is required before the output of a Grove et al. '901 device might be said to be reduced to an "eye-safe"

level, is an acknowledgement that for distances less than a mile, the emitted light is not at an "eye safe" level.

As discussed in the subject application at page 47, line 20 through page 48, line 4, the determination as to whether a laser or other light source is eye-safe is based on a comparison of (a) the fluence that would be produced by the device at the cornea (F_{cornea}) when measured according to international standards, and (b) the MPE for the device, calculated using its parameters such as wavelength, pulse duration, etc. That is, to be eye-safe a device must produce a fluence at the cornea below the MPE, not at any arbitrary distance (such as a mile or more, in which case virtually every laser would be eye-safe), but when F_{cornea} is measured in a certain way based on established standards that take in to account all possible distances between the device an the eye of a user or bystander. It is respectfully submitted that, by these established standards, F_{cornea} in the device taught by Grove et al. '901 would exceed the MPE by orders of magnitude, resulting in its classification by the CDRH-FDA as a Class IV laser, an extreme eye-hazard. Applicants submit that, in contrast, a device constructed in accordance with the invention described in the subject application has been determined to be a CDRH Class I (eye-safe) laser device by one of the world's experts in laser safety in an independent test. The device of Grove et al. '901 is therefore fundamentally different from the device of claims 1 and 31.

For the foregoing reasons, it is respectfully submitted that independent claims 1 and 31 are allowable, and that claims 2, 5, 8, 16-18, 20-30, 31-34, and 36-44 as dependent from claims 1 and 31, are also allowable, and the Examiner's indication to that end is respectfully solicited.

Rejection under 35 U.S.C. 103(a) -- 45-70 (Grove et al. '901 and '403)

The Examiner has cited the combination of Grove et al. '901 and Grove et al. '403 to reject claims 45-70 as obvious under 35 U.S.C. 103(a). Applicants traverse this rejection for the following reasons. First, the Examiner relies upon "the diffractive diffuser of Grove et al. '901" as an element for which a "reflective diffuser" may be substituted. *See,* page 3 of the Official Action. However, it is respectfully submitted that

Grove et al. '901 do not teach a diffractive diffuser. The undersigned attorney has not been able to locate such words in the text of Grove et al. '901, nor any discussion in Grove et al. '901 which might be characterized as relating to optical diffusers. In contrast, see the discussion of diffusers found in the subject application at, for example, page 15, lines 4-12; page 15 line 22 to page 18, line 3; page 18, line 17 to page 20 line 14; and page 21, lines 1-18. While Grove et al. '901 discuss a "condenser 38" at column 6, line 29 to column 7, line 2, it is respectfully submitted, however, that such a structure is not a "diffractive diffuser, and is more like the "mixer" discussed in the subject application. *See*, for example, page 21, line 24 to page 22, line 28, of the subject application.

Further, Applicants respectfully submit that even if a "reflective diffuser" element were incorporated into the device described in Grove et al. '901, as asserted by the Examiner, the resulting device would be rendered inoperable. Such a reflective diffuser would send light back in to the non-imaging condenser 38 (Column 6, line 31, Grove et al. '901) at all angles. This type of condenser remits light from its output face only for rays highly directed toward its output face (note that the diode laser arrays 12A – 12F shown in Figure 1 of Grove et al. '901 are oriented to point directly toward the output face of the condenser 38 in contact with the skin). Also, incorporation of a reflective diffuser at any location between the diode laser arrays and the output face of Grove et al. '901 would cause light to circulate and ultimately be absorbed within the non-imaging condenser 38, drastically reducing the output fluence of the device in a manner contrary to the teaching of Grove et al. '901 to use microlenses to obtain increased effective brightness of the array and condenser 38 to increase output fluence (i.e., decreasing the overall area of emission utilizing the increased effective brightness made possible by the microlensed array). *See*, Grove et al. '901, column 6, lines 4-10, and lines 46-51.

Thus, for the foregoing reasons, it is respectfully submitted that it would not be obvious to make the combination of Grove et al. '901 and Grove et al. '403 as asserted by the Examiner.

Rejection under U.S.C. 103(a) -- 3, 4, and 11-15 (Grove et al. '403 and Rosow)

Applicants respectfully traverse the Examiner's rejection of claims 3, 4, and 11-15 under U.S.C. 103(a) as being unpatentable over Grove et al ('903) [believed to be Grove et al. '901] in combination with USP 5,966,210 to Rosow et al. for reasons similar to those set forth above in traversing the Examiner's rejection of claims 45-70 over Grove et al '901 in view of Grove et al. '403. Simply put, Grove et al. '901 does not teach the use of an optical diffuser, much less a transmissive diffuser. The use of such a diffuser in Grove et al. '901 would be contrary to the teaching of Grove et al. '901 to use microlenses and condenser 38 to obtain increased brightness and to reduce the illumination area while maintaining most of the energy. *See*, Grove et al. '901, column 6, lines 4-10, and lines 46-51.

Applicants submit that a transmissive diffuser such as opal glass works as a diffuser by redirecting light incident upon it into all angles. If such a diffuser were incorporated into the device of Grove et al. '901, light from the diode laser arrays impinging on such a diffuser, rather than remaining directed toward the output aperture of the condenser, would strike the inside walls of the condenser at all angles. This would result in much of the light being redirected back toward the arrays. Such a result would be contrary to the design of the lenslet array described in Grove et al. '901 which was fabricated with precision to ensure that light emitted from each diode laser array suffered as few reflections as possible off of the condenser walls to maximize throughput. *See*, Grove et al. '901, column 6, lines 4-51, for example.
For the above reasons, it is respectfully submitted that claims 3-4 and 11-15 are allowable over Grove et al. '901 in view of Rosow et al.

Rejection under U.S.C. 103(a) -- 6, 7, 9, 10, 19 and 35 (Grove et al. '403 and McDaniel)

Applicants respectfully traverse the Examiner rejection of claims 6, 7, 9, 10, 19 and 35 under 35 U.S.C. 103(a) as being unpatentable over Grove et al ('903) [believed to be Grove et al. '901] in view of USP 5,663,659 to McDaniel. First of all, Applicants disagree that Grove et al. '901 teaches the use of optical diffusers as asserted by the

Examiner in the preceding sections of the Official Action. *See,* the Applicants' discussions of Grove et al. '901 in the preceding sections of this paper.

Furthermore, McDaniel teaches a biostimulative approach to dermatologic treatment that specifically avoids thermal injury to human tissue. *See*, for example, McDaniel column 3, line 36 to column 4, line 7. Thus, when compared with the primary thrust of Grove et al. '901 to provide increased brightness, minimized divergence, and increase throughput, for high output fluence levels, it can be seen that McDaniel's opposite approach of biostimulation that avoids thermal injury to human tissue effectively counteracts any motivation to combine the two references.

In contrast to both Grove et al. '901 and McDaniel, the device and method described in the subject application instead employs such thermal injury to effect desired results, such as hair regrowth inhibition. *See*, page 6, lines 14-24, for example. Thus, even if the teachings of McDaniel were applied to the device of Grove et al. '901 to produce the energy levels relied upon in McDaniel, it is respectfully submitted that the resulting energy levels would not meet the "not less than 4 J/cm^2" output fluence levels recited in rejected claims 6, 7, 9, 10, 19 and 35. Thus, the combination of Grove et al. '901 and McDaniel relied upon by the Examiner lack not only any motivation to combine them, but also at least the optical diffusers, and the provision of "not less than 4 J/cm^2" output fluence levels, as recited in independent claims 1 or 31 from which claims 6, 7, 9, 10, 19 and 35 depend.

For at least these foregoing reasons, it is respectfully submitted that it would not be obvious to combine Grove et al. '901 with McDaniel as asserted by the Examiner, and that claims 6, 7, 9, 10, 19 and 35, are allowable over these references.

Conclusions

It is for the foregoing reasons that it is respectfully submitted that the claimed invention is patentable and allowable over the cited references, and the Examiner's indication to that end is respectfully solicited.

The undersigned attorney would welcome a call from the Examiner should the Examiner require clarification or wish to discuss any of the points raised in this

Amendment, or to discuss other actions which might be taken to advance the subject application to allowance.

Respectfully submitted,

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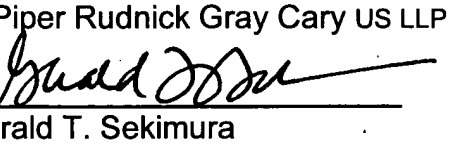
By: 

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